

*E. Safety Determination*

1. *U.S. population.* Based on a complete and reliable toxicology database, the acceptable reference dose RfD is 0.010 mg/kg/day, based on a LOEL of 5.0 mg/kg/day from the chronic dog study and an uncertainty factor of 100. Available information on anticipated residues, monitoring data and percent crop treated was incorporated into an analysis to estimate the Anticipated Residue Contribution (ARC) for 26 population subgroups. The ARC is generally considered a more realistic estimate than an estimate based on tolerance level residues. The ARC are estimated to be 0.000025 mg/kg body weight (bwt)/day and utilize 0.3 percent of the RfD for the overall U. S. population. The ARC for non-nursing infants (<1 year) and children 1–6 years old (subgroups most highly exposed) are estimated to be 0.000014 mg/kg bwt/day and 0.000042 mg/kg bwt/day and utilizes 0.1 percent and 0.4 percent of the RfD, respectively. Generally speaking, the EPA has no cause for concern if the total dietary exposure from residues for uses for which there are published and proposed tolerances is less than 100 percent of the RfD. Therefore, FMC concludes that the chronic dietary risk of cypermethrin, as estimated by the aggregate risk assessment, does not appear to pose significant risk.

For the overall U.S. population, the calculated margins of exposure (MOE) at the 95th percentile was estimated to be 2,047; 496 at the 99th percentile; and 225 at the 99.9th percentile. For all infants < one year old, the calculated MOE at the 95th percentile was estimated to be 14,240; 2,902 at the 99th percentile; and 1,003 at the 99.9th percentile. For nursing infants < one year old, the calculated margins of exposure (MOE) at the 95th percentile was estimated to be 30,026; 4,144 at the 99th percentile; and 714 at the 99.9th percentile. For non-nursing infants < one year old, the calculated margins of exposure (MOE) at the 95th percentile was estimated to be 13,331; 2,667 at the 99th percentile; and 1,337 at the 99.9th percentile. For the most highly exposed population subgroup, children 1 – 6 years old, the calculated MOE at the 95th percentile was estimated to be 2,767; 479 at the 99th percentile; and 183 at the 99.9th percentile. Therefore, FMC concludes that there is reasonable certainty that no harm will result from acute exposure to cypermethrin.

2. *Infants and children.* —a. *General.* In assessing the potential for additional sensitivity of infants and children to residues of cypermethrin, FMC

considered data from developmental toxicity studies in the rat and rabbit, and a three-generation reproductive study in the rat. The data demonstrated no indication of increased sensitivity of rats or rabbits to in utero and/or postnatal exposure to cypermethrin. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from pesticide exposure during prenatal development to one or both parents. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity. FFDCA section 408 provides that EPA may apply an additional margin of safety for infants and children in the case of threshold effects to account for pre- and post-natal toxicity and the completeness of the database.

b. *Developmental toxicity studies.* In the prenatal developmental toxicity studies in rats and rabbits, there was no evidence of developmental toxicity at the highest doses tested (70 mg/kg/day in rats and 700 mg/kg/day in rabbits). Decreased body weight gain was observed at the maternal LOEL in each study; the maternal NOEL was established at 17.5 mg/kg/day in rats and 100 mg/kg/day in rabbits.

c. *Reproductive toxicity study.* In the 3-generation reproduction study in rats, offspring toxicity (reduced mean litter weight gain) was observed only at the highest dietary level tested (37.5 mg/kg/day), while toxicity in the parental animals was observed at the lower treatment levels. The parental systemic NOEL was 2.5 mg/kg/day and the parental systemic LOEL was 7.5 mg/kg/day. There were no developmental (pup) or reproductive effects up to 37.5 mg/kg/day (highest dose tested).

d. *Pre- and post-natal sensitivity.* —i. *Pre-natal.* There was no evidence of developmental toxicity in the studies at the highest doses tested in the rat (70 mg/kg/day) or in the rabbit (700 mg/kg/day). Therefore, there is no evidence of a special dietary risk (either acute or chronic) for infants and children which would require an additional safety factor.

ii. *Post-natal.* Based on the absence of pup toxicity up to dose levels which produced toxicity in the parental animals, there is no evidence of special post-natal sensitivity to infants and children in the rat reproduction study.

Based on the above, FMC concludes that reliable data support use of the standard 100-fold uncertainty factor, and that an additional uncertainty factor is not needed to protect the safety of infants and children. As stated above,

aggregate exposure assessments utilized significantly less than 1 percent of the RfD for either the entire U. S. population or any of the 26 population subgroups including infants and children. Therefore, FMC concludes that there is reasonable certainty that no harm will result to infants and children from aggregate exposure to cypermethrin residues.

*F. International Tolerances*

There are no codex, Canadian, or Mexican residue limits for residues of cypermethrin in or on green onions.

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**FEDERAL HOUSING FINANCE BOARD****Announcing an Open Meeting of the Board**

**TIME AND DATE:** 10:00 a.m., Wednesday, March 25, 1998.

**PLACE:** Board Room, Second Floor, Federal Housing Finance Board, 1777 F Street, N.W., Washington, D.C. 20006.

**STATUS:** The entire meeting will be open to the public.

**MATTERS TO BE CONSIDERED DURING PORTIONS OPEN TO THE PUBLIC:**

- FHLBank Investment Practices and Implications for Finance Board Investment Policy.
- Final Rule: Eligibility for Membership and Advances.
- Proposed Rule: Elections Regulations.
- Office of Finance—Board Compensation Policy Approval.
- Office of Finance—Board Appointments.

**CONTACT PERSON FOR MORE INFORMATION:** Elaine L. Baker, Secretary to the Board, (202) 408–2837.

**William W. Ginsberg,**

*Managing Director.*

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**FEDERAL RESERVE SYSTEM****Change in Bank Control Notices; Acquisitions of Shares of Banks or Bank Holding Companies**

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).